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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/784,046	02/20/2004	Claude Mathieu	8932-823-999	6834

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EXAMINER

PELLEGRINO, BRIAN E

ART UNIT	PAPER NUMBER
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3738

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/784,046

Applicant(s)

MATHIEU ET AL.

Examiner

Brian E. Pellegrino

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 60-80 is/are pending in the application.
- 4a) Of the above claim(s) 62,63 and 65-68 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 60,61,64 and 69-80 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Allowable Subject Matter

The indicated allowability of claims 60,61,64,69-80 is withdrawn in view of the newly discovered reference(s) to Walston et al. (5491882). Rejections based on the newly cited reference(s) follow.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the coupling portion ...configured to be deformable....with the deformed diameter being between about 10% to about 50% of the unstressed diameter. There is no description to explain what embodiment is capable of having this capability.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 74,75 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 74 recites the "coupling portions are configured to substantially prevent compression of the interspinal space....". However,

claim 60 recites that the "coupling portion of the halves are configured to be deformable...". How is it possible that the coupling can deform yet prevent compression?

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 60,61,64,69,70,74,75,77 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Walston et al. (5491882). Walston et al. disclose a prosthesis for implantation between two joint bones, col. 2, lines 57-59. It is fully capable of being used as an interspinal prosthesis. Fig. 10 shows a first half **109** with a coupling portion having a bore and a process portion sized and configured to be placed on one side of a spinous process with a flat surface bone engaging surface and an opposing flat stop surface and is also configured to prevent its advancement into the interspinal space as a result of its bone anchor. It can also be seen there is a second half which *comprises* a coupling portion **108** configured to be received within the bore of the first half. The Examiner interprets the process portion **107** to be part of the second half since the claims do not exclude multiple components to form a "half" of a prosthesis. Process portion **107** is analogous to the description for first half in its functions. The Examiner also interprets the stems **106,108** to provide an axial locking mechanism since they prevent any movement of the halves with respect to one another, col. 5, lines 36-39. The claim does not define the

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axis. Walston et al. also disclose the coupling portion is elastically deformable such that it can be interpreted that it can be deformed (col. 4, lines 45,46) such that it is capable of deforming to about 50% of its unstressed diameter depending on the stresses placed thereon. Walston et al. additionally disclose the coupling portion can be any size, col. 6, lines 46,47. The device is fully capable of being inserted in the unassembled condition to couple together to an assembled condition. Regarding claim 64, Walston discloses rotation is prevented as a result of the "key and keyway" type of configuration, col. 5, lines 38,39. With respect to claim 69, since Walston discloses the coupling half is like a marshmallow, the Examiner considers it to be "elastomeric", col. 4, lines 45,46. Regarding claim 70, Walston discloses the half **109** is metal, col. 5, line 37. Regarding claim 74 as best understood, upon insertion of the device in the interspinal space, since it is taking up some of the space, it must "substantially prevent compression." With respect to claim 75, since the stems (107,109) would be anchored in bone, they retain the coupling portions within the interspinal space.

However, in the alternative Walston et al. does not disclose explicitly a locking mechanism per se. It is well known in the art to use threads on telescoping members such that axial movement is prevented. It would have been obvious to one of ordinary skill in the art to incorporate threads on the stems to prevent any sliding in the longitudinal direction on the prosthesis of Walston et al. such that it keeps the device stable at the site of repair and allows for normal range of motion.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 60,61,64,69,70,74-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zucherman et al. (5836948) in view of Walston et al. '882. Zucherman et al. disclose (Figs. 21,22) an interspinal prosthesis for implantation between a first spinous process **376** and a second spinous process **378** having two halves (**372,374**) that are locked together axially using a locking mechanism **380** through a bore in the halves. However, Zucherman fails to disclose the embodiment discussed above has the second half of the prosthesis configured to be received in the bore of the first half or the deformation potential of the material. It is noted that Zucherman discloses (Fig. 16) an embodiment with a second half **134** that is configured with projection **152** to be received in the bore **154** of the first half **132**. It would have been obvious to one of ordinary skill in the art to utilize the coupling configuration of Fig. 16 to include a projection to be inserted in bore of the first half of the embodiment of Fig. 22 such that it prevents any misalignment. It is also noted that Zucherman discloses the material of the halves is elastically deformable or flexible, col. 7, lines 11-14, col. 11, lines 56-58. Walston et al. is explained supra. It would have been obvious to one of ordinary skill in the art to utilize a highly compressible material to deform at least about 50% as taught by Walston et al. with the spinous implant of Zucherman et al. such that it mimics the movement of the spinous process joint area. Regarding claim 61, the two

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halves are fully capable of being inserted unassembled and then coupled to the assembled form. With respect to claims 64,76 Zucherman shows (Fig. 19) an embodiment with two halves having complementary key or tab and keyway or groove surfaces that would prevent rotation. It would have been obvious to one of ordinary skill in the art to utilize alternative connection means such as key or tab and keyway or groove type of couplings to join two prosthetic halves with the deformable embodiment such that it limits rotation. With respect to claim 70, Zucherman discloses materials for the implant can be metal, col. 4, lines 17-19. Regarding claim 78, Zucherman discloses the interspinous body can have a height of about 10mm (col. 14, lines 2,3) which falls within the claimed range of 2-15mm. Regarding claims 79,80 Zucherman does mention widths for the prosthetic halves, col. 14, lines 51-61 but fails to explicitly disclose the range of cross-sectional dimensions of the coupling portions or the dimensions of the process portions. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a cross-sectional dimension 50mm^2 to 300mm^2 for the coupling portions or a range between 70mm^2 to 500mm^2 for the cross sectional dimension of the process portions, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Claims 71-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walston et al. '882 in view of Taylor (WO 95/31158). Walston is explained above. However, Walston fails to disclose a hydroxyapatite coating on the exterior surface of

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the process portions. Taylor teaches the use of a hydroxyapatite coating on the surface to promote bone ingrowth, abstract. It would have been obvious to one of ordinary skill in the art to coat the surface with hydroxyapatite as taught by Taylor on the implant of Walston such that it enhances osteo-integration and prevents any migration out of the bore in the bone.

Response to Arguments

Applicant's arguments with respect to claim 60 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M-Fr (8:30am-5pm). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700, AU 3738



BRIAN E. PELLEGRINO
PRIMARY EXAMINER